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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/913,555	09/19/97	KAYAGAKI	N 715-118

020277  
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600 13TH STREET NW  
WASHINGTON DC 20005-3096

HM12/0401

EXAMINER

TUNG, M

ART UNIT	PAPER NUMBER
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1644

12

DATE MAILED: 04/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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# Office Action Summary

Application No.

08/913,555

Applicant(s)

Kayagaki, et al.

Examiner

Mary Tung

Group Art Unit

1644



☒ Responsive to communication(s) filed on 11/30/98, 1/13/99 and 1/14/99

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 51-154 is/are pending in the application.

Of the above, claim(s) 63-72 and 76-153 is/are withdrawn from consideration.

☒ Claim(s) 51-53, 55-62, 73-75, and 154 is/are allowed.

☒ Claim(s) 54 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☒ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

**DETAILED ACTION**

1. Claims 1-50 were cancelled in the paper filed September 19, 1997 (Paper No. 3).
2. Claims 51-154 were added in Paper No. 3. It is noted that the replacement sheets filed in PCT/JP96/00734, filed December 24, 1996, resulted in the cancellation of claims 51-56, as communicated to applicants in the preliminary search report completed on March 4, 1997. The preliminary amendment filed September 19, 1997 failed to present the cancelled claims 51-56 for consideration in the instant application, filed under 35 U.S.C. 371. *Therefore, the numbering and consideration of the claims, set forth in the action mailed May 28, 1998 is maintained.* The requested changes in claim numbering in claims 52, 54, 56-62, 74 and 75 (listed as claims 58, 60, 62-68, 80 and 81 by the applicant on pages 4 and 5 of Paper No. 7) has been changed by the Examiner under Rule 1.26 to reflect the proper numbering of the claims.
3. Claims 51-154 are pending.

**Election/Restriction**

4. Applicant's confirmation of the election with traverse of Group I, claims 51-65, 69-78, 82-85, 87, 88, 90, 91, 93, 94, 96, 97, 99, 100, 102, 103, 105, 106, 108, 109, 111, 113, 115, 117, 119, 121, 123, 124, 126, 127, 129, 130, 132, 133, 135, 136, 138, 139, 141, 142, 144, 145, 147, 148, 150, 151, 153, and 154, and the *specific embodiment recited in claims 51-57, the method of using said antibodies, recited in claims 58-60, a kit recited in claims 61 and 62 and a process for making the antibody, recited in claims 73-75 and 154* (listed as claims 57-68, 79-81 and 160 by the applicant on page 6, paragraph 2 of Paper No. 7) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
5. Applicant has further elected with traverse in Paper No. 7, the species of six monoclonal antibodies as set forth at pages 37-44 of the specification. The traversal is on the ground(s) that it would not be unduly burdensome to search the related monoclonal antibodies of the claimed invention. However, the antibodies are distinct products, with different physical properties and uses, and are therefore patentably distinct. Claims 63-72 and 76-153 (claims drawn to Groups II and III and non-elected embodiments recited in Group I) are patentably distinct and are accordingly held to be withdrawn from further consideration under 37 C.F.R. 1.142(b).
6. The requirement is still deemed proper and is therefore made FINAL.

*In light of the paper filed November 30, 1998, only the following rejection remains:*

7. Applicant's arguments filed 11/30/98 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 112***

8. Claim 54 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the same reasons set forth in the action mailed May 28, 1998.

9. The applicants argue that one of ordinary skill in the art can obtain the Fas/WR19L cell line by following the procedure disclosed in Hanabuchi, et al., *PNAS USA*, 91:4930-4934, 1994 and simply substituting the human Fas gene and WR19L cells for mouse Fas gene and 15178Y cell and that WR19L cells are publically available from ATCC (ATCC TIB52). However, the limitations of the claim appear to require the use of the Fas/WR19L cell line in particular and due to variations in cloning procedures, insertion sites, and so forth, to obtain the particular claimed cell line would be difficult if not impossible. Therefore, it is apparent that the Fas/WR19L cell line recited in claim 54 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of said cell line. See 37 CFR 1.802. Additionally, the applicants failed to properly incorporate by reference the Hanabuchi reference. As stated in *MPEP 608.01(p)*, the mere mention of reference is not an incorporation of the subject matter into the specification. Therefore, the applicants are required to comply with the rules for deposit of Biological material as discussed in the action mailed May 18, 1998.

***MPEP 608.01(p)***

**INCORPORATION BY REFERENCE**

The Commissioner has considerable discretion in determining what may or may not be incorporated by reference in a patent application. *General Electric Co. v. Brenner*, 407 F.2d 1258, 159 USPQ 335 (D.C. Cir. 1968). The following is the manner in which the Commissioner has elected to exercise that discretion. Section 1 provides the guidance for incorporation by reference in applications which are to issue as U.S. patents. Section 2 provides guidance for incorporation by reference in benefit applications; i.e., those domestic (35 U.S.C. 120) or foreign (35 U.S.C. 119) applications relied on to establish an earlier effective filing date.

Nonessential subject matter may be incorporated by reference to (1) patents or applications published by the United States or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications, or (3) non - patent publications. Nonessential subject matter is subject matter referred to for purposes of indicating the background of the invention or illustrating the state of the art.

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144, (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. Guidelines for situations where applicant is permitted to fill in a number for Serial No. \_\_\_\_\_ left blank in the application as filed can be found in *In re Fouche*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971) (Abandoned applications less than 20 years old can be incorporated by reference to same extent as copending applications; both types are open to public upon referencing application issuing as a patent).

### *Allowable Subject Matter*

10. Claims 51-53, 55-62, 73-75 and 154 are allowed.

### *Conclusion*

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

12. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

26. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). **THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.**
26. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Monday through Friday from 8:30 am to 5:30 pm. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

Serial No. 08/913,555  
Art Unit 1644

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March 29, 1999  
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Patent Examiner  
Group 1640

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ART UNIT 182 1644